Memorandum: Coag #33

To: UNC Health System Attending Physicians, Faculty Practice Physicians, Housestaff, Clinical Nurse Coordinators, Department Heads and Supervisors

From: Herbert C. Whinna, MD, PhD
Medical Director, McLendon Clinical Laboratories

Date: November 18, 2025

Subject: Anti-Cardiolipin and Anti-Beta$_2$ Glycoprotein 1 Antibodies Testing Methodology Change

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Effective 1-Dec-2025 the Special Coagulation Laboratory of UNCH McLendon Clinical Laboratories will change the Anti-Cardiolipin and Anti-Beta2 Glycoprotein 1 Antibodies Testing Methodology to the Quanta Flash from Inova Diagnostics. This will result in two main advantages:

1. All assay standards are traceable back to internationally recommended[1] standards for these assays.

2. All assays will have the same Upper Limit of Normal (20.0) above which results will reflect a value >99th percentile of normal controls in accordance with the 2025 ISTH GUIDEANCE AND GUIDELINES[2].

Additionally, the sample type will change from plasma (Light Blue -NaCitrate tube) to serum (Gold-SST tube) which will align our laboratory protocol with other hospital and reference laboratories. All Epic Orders will stay the same and the sample change will happen automatically in Epic.

Because of the inherent heterogeneity of Anti-Cardiolipin and Anti-Beta$_2$ Glycoprotein 1 antibodies, results from these assays may not always match results from previous/other methodologies either quantitatively or qualitatively.

For questions related to these changes, you can contact Herbert Whinna via Epic In-Basket or email me at: Herbert.Whinna@unchealth.unc.edu.

References

1. Miyakis S, Lockshin MD, Atsumi T, Branch DW, Brey RL, Cervera R, Derksen RHWM, de Groot PG, Koike T, Meroni PL, Reber G, Shoenfeld Y, Tincani A, Vlachoyiannopoulos PG, Krilis SA. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J Thromb Haemost 2006; 4: 295–306.

2. Devreese KMJ, Bertolaccini ML, Branch DW, de Laat B, Erkan D, Favaloro EJ, Pengo V, Ortel TL, Wahl D, Cohen H. An update on laboratory detection and interpretation of antiphospholipid antibodies for diagnosis of antiphospholipid syndrome: guidance from the ISTH-SSC Subcommittee on Lupus Anticoagulant/Antiphospholipid Antibodies. J Thromb Haemost. 2025 Feb;23(2):731-744. doi: 10.1016/j.jtha.2024.10.022. Epub 2024 Nov 5. PMID: 39510414.